

Claims

What is claimed is:

- 1 1. A process for manufacturing a tissue implant comprising obtaining tissue to be
2 processed; scanning said tissue to produce dimensional data of said tissue; analyzing
3 said data by a computer system enabled with a database comprising a plurality of
4 designs; and identifying one or more designs and quantity thereof that relate to an
5 optimized use of said tissue, whereby one or more tissue products are produced in
6 accord with said identified one or more designs and quantity thereof.
- 1 2. The process according to claim 1, wherein said at least one tissue sample is sterilized.
- 1 3. The process according to claim 1, wherein said at least one tissue sample is allograft,
2 autograft, or xenograft tissue, or combinations thereof.
- 1 4. The process according to claim 3, wherein said at least one tissue sample is cortical
2 bone, cancellous bone, fascia, dermis, whole joints, tendons, ligaments, dura,
3 pericardia, heart valves, veins, neural tissue, or submucosal tissue, cartilage, or
4 combinations thereof.
- 1 5. A process for manufacturing tissue implants comprising:
2 a. obtaining at least one tissue sample for processing;
3 b. sterilizing said at least one tissue sample;
4 c. scanning said at least one tissue sample to produce dimensional data
5 corresponding thereto;
6 d. inputting said data into a computer system enabled with a database comprising
7 a plurality of designs;
8 e. identifying one or more designs and quantity thereof that correspond to an
9 optimal use of said at least one tissue sample; and

10 f. machining said at least on sample of tissue to produce one or more tissue
11 products in accord with said one or more designs and quantity thereof.

1 6. The process according to claim 5, wherein said at least one tissue sample is allograft,
2 autograft, or xenograft tissue, or combinations thereof.

1 7. The process according to claim 6, wherein said at least one tissue sample is cortical
2 bone, cancellous bone, fascia, whole joints, tendons, ligaments, dura, pericardia, heart
3 valves, veins, neural tissue, submucosal tissue, dermis, or cartilage, or combinations
4 thereof.

1 8. The process according to claim 5, wherein said sterilization is achieved through a
2 process that retains the bioactive properties of said at least one tissue sample.

1 9. The process according to claim 8, wherein said sterilization is achieved using a
2 process selected from the group consisting of BioCleanse, acid wash, boiling, 100%
3 ethanol, gamma radiation, ethylene oxide, disinfectants, broad spectrum antibiotic
4 solutions or combinations thereof.

1 10. The process according to claim 5, wherein said scanning comprises disposing said at
2 least one tissue sample in a container that interfaces with at least one scanning device
3 positioned in, on, or proximate to said container to effectuate scanning of said tissue
4 sample.

1 11. The process of claim 10, wherein said scanning device is enabled to scan said at least
2 one tissue sample in x, y, or z coordinate planes, or combinations thereof.

1 12. The process of claim 11, wherein said scanning device generates dimensional data
2 corresponding to the size and shape of said scanned tissue sample.

- 1 13. The process according to claim 5, wherein said computer system is enabled with a
2 graphical software program designed to produce images.
- 1 14. The process according to claim 13, wherein said dimensional data is converted into
2 numerical data.
- 1 15. The process of claim 14, wherein said numerical data is converted into an image by
2 said graphical software program.
- 1 16. The process of claim 5, wherein said identifying step utilizes an algorithm to match
2 said data with one or more preferred designs from said database relating to an optimal
3 use of said tissue sample.
- 1 17. The process of claim 16, wherein said data is matched with said one or more
2 preferred designs based on similarity of dimensions.
- 1 18. The process of claim 5, wherein said database is generated from compiling
2 dimensional data from previously manufactured tissue implants.
- 1 19. The process of claim 5, wherein upon identifying said one or more template designs
2 and number thereof, said at least one tissue sample is directed to a specific
3 machining device selected from a plurality of machining devices, wherein said
4 specific machining device is configured to machine said sorted tissue in accord with
5 said template design.
- 1 20. The process of claim 5, further comprising cutting said at least one tissue sample into
2 a blank prior to said machining, whereby said blank is cut to have dimensions
3 appropriate for subsequent machining into said one or more designs and quantity
4 thereof.

- 1 21. The process of claim 20, wherein said machining is conducted by a milling device
2 that is contained in its own environment to thereby prevent contamination from the
3 environment external to said milling device.
- 1 22. The process of claim 5, wherein said process further comprises inspecting said one or
2 more tissue products for quality verification.
- 1 23. The process of claim 22, wherein said inspecting is conducted by optical inspection
2 wherein cameras are positioned for remote viewing of said one or more tissue
3 products
- 1 24. The process of claim 23, wherein said optical inspection comprises utilizing a
2 plurality of video cameras, mounted such that separate x, y and z coordinate planes
3 along said product may be viewed optically to ensure complete inspection of the
4 product quality to accept or reject said product.
- 1 25. The process of claim 5 comprising packaging said one or more tissue products.
- 1 26. The process of claim 25, further comprising sterilizing said one or more tissue
2 products by irradiation.
- 1 27. The process of claim 5, wherein sterilizing of at least one tissue sample comprises
2 disposing said at least one tissue sample in a chamber and sterilizing said tissue in
3 said chamber; and scanning said at least one tissue sample comprises scanning in
4 said chamber, such that said at least one tissue sample remains sterilized during said
5 scanning step.
- 1 28. The process of claim 5, wherein said at least one tissue sample is transferred between
2 steps in sterilized containers.

1 29. The process of claim 5, wherein subsequent to machining said at least one tissue
2 sample, said tissue is packaged, sterilized and stored.

1 30. The process according to claim 29, wherein package sterilization is achieved through
2 Sterrad sterilization procedures.

1 31. An automated tissue processing system comprising:
2 a sterilization chamber; an optimizer unit comprising at least one scanning device
3 interfaced with at least one computer system enabled by at least one analytical
4 software program and a database comprising a plurality of template designs; a cutting
5 device for cutting tissue into a desired tissue blank; a routing device for routing said
6 tissue to an appropriate milling machine for machining said blank into a desired
7 product; an inspection station for inspecting the quality of said product; a holding
8 chamber for holding rejected products; a packaging station for packaging and labeling
9 accepted products; and a storage station for storing products prior to shipment.

1 32. An automated process for manufacturing implantable tissue products
2 comprising:

3 (a) selecting a tissue sample for processing; placing said tissue sample into a
4 sterilized chamber, wherein said tissue sample is sterilized;

5 (b) transferring said sterilized tissue sample into a sterilized optimizer unit,
6 wherein said tissue sample is scanned to obtain dimensional data
7 corresponding to said tissue sample;

8 (c) inputting dimensional data from said sample into a computer system enabled
9 with an analytical software program and a database comprising a plurality of
10 designs;

11 (d) analyzing said dimensional data with said analytical software program to
12 identify a design type and quantity thereof commensurate with the dimensions
13 of said tissue sample to maximize tissue utilization;

- 14 (f) routing said tissue sample into a sterilized cutting machine wherein said tissue
15 sample is cut into a tissue blank of sufficient size and shape to facilitate
16 subsequent machining of said tissue product according to said design;
17 (g) transporting said container to a sorter;
18 (h) placing said blank into said sorter, wherein said blank is routed to a milling
19 device enabled to machine a design from the blank in accord with said
20 identified design and quantity thereof;
21 (i) milling said blank to produce a finished product in accord with said identified
22 template design and number thereof;
23 (j) analyzing said finished product for quality;
24 (k) packaging and labeling said finished product;
25 (l) sterilizing said packaged product prior to storage; and
26 (m) storing said sterilized product for at least twenty-four hours.

1 33 An implant produced by the process of claim 1.

1 34 An implant produced by the process of claim 5.

1 35 A process for manufacturing tissue implants comprising:

- 2 a. scanning at least one tissue sample to produce dimensional data corresponding
3 thereto;
4 b. inputting said data into a computer system enabled with a database comprising
5 a plurality of designs;
6 c. identifying one or more designs and quantity thereof that correspond to an
7 optimal use of said at least one tissue sample; and
8 d. routing said at least one tissue sample to a machining device, wherein said
9 machining device is programmed with the specifications of said identified
10 design to automatically machine said at least one tissue sample to produce a
11 tissue product in accord with said identified design.